Rare cancer responds unusually well to new treatment

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Vienna, Austria: Patients with advanced gastrointestinal neuroendocrine tumours (NETs) have limited treatment options and there are few oncologists who are specialised in this relatively rare disease. But now results from a multi-centre randomised international trial of an innovative treatment show a marked improvement in the length of time patients with mid-gut NETs live without the disease getting worse (progression-free survival, or PFS), researchers will report to the 2015 European Cancer Congress today.

Professor Philippe Ruszniewski, MD, Head of the Department of Gastroenterology-Pancreatology, Beaujon Hospital, Clichy, France, who is also a Professor at Paris Diderot University, will tell the Congress that results of the NETTER-1 phase III trial of 177Lu-DOTATATE (Lutathera) show a PFS that has never been shown before in this type of cancer. "Because these patients have a real unmet medical need, this is particularly pleasing for us," he says.

Lutathera is a member of the family of novel treatments called Peptide Receptor Radionuclide Therapy (PRRTs) which involve targeting tumours with radiolabelled somatostatin analogue (SSA) peptides. The technique belongs to the larger family of molecular nuclear medicine, where trace amounts of active substances, or radiopharmaceuticals, are used to create images and to treat various diseases including cancer. SSAs are widely used in gastrointestinal NETs cancer to reduce symptoms such as diarrhoea.

The trial recruited 230 patients from 36 sites in eight European countries and 15 centres in the US. All patients had mid-gut NETs that had spread to other parts of the body (metastasised), and had already undergone SSA treatment. They were randomised to receive either Lutathera combined with the somatostatin Octreotide LAR, the current standard of care in mid-gut NETs, or Octreotide LAR alone. The primary endpoint of the trial was PFS, while secondary endpoints included overall survival (OS), safety and quality of life, among others.

"Our results confirmed data from phase I and II trials," Prof Ruszniewski will say. "At the time we analysed the data, the median PFS for Lutathera had not been reached, whereas we could define it as 8.4 months in patients who received Octreotide LAR alone. Results so far show that patients on Lutathera are achieving extra time without their disease progressing. This kind of PFS is rarely achieved in cancer. We also have been able to see that Lutathera has a good safety profile and offers these patients a good quality of life.

"From a payer's point of view, there are significant advantages too. By the use of a scintigraphy, Lutathera enables us to identify the patients who are eligible for treatment and who should respond positively to it. This should lead to substantial savings and ensure that most patients who receive the treatment are likely to respond."

Lutathera is injected intravenously, and Octreotide LAR into the buttocks (deep intragluteal injection). Patients in the Lutathera group received four doses over eight weeks, plus 30 mg of Octreotide LAR every 28 days. Patients in the Octreotide LAR alone group receive 60 mg of the drug every four weeks. PFS is analysed every 12 weeks, and patients remain in the study until their disease progresses, there is unacceptable toxicity, or they wish to withdraw for their own reasons.

Mid-gut NETs are rare, with an incidence generally estimated to be

around five in every 100,000 cancers. All NETs are classified as rare diseases by regulatory authorities in the EU and US. "This means that there are few drugs available to treat these patients, and why we are particularly excited to have found something with what appears to be such a long-lasting effect - the PFS we have seen has not been reached before in this type of disease and patient population," says Prof Ruszniewski.

"Now, apart from making the drug available through submitting it for approval by the regulatory authorities, we would like to see additional studies investigating its efficacy in other types of NETs, for example, pancreatic and bronchial."

Professor Peter Naredi, the ECCO scientific co-chair of the Congress, who was not involved in the research, commented: "Professor Ruszniewski and co-workers must be congratulated for this phase III study where 177Lu-DOTATATE has been shown to be superior to Octreotide LAR in patients with metastasised mid-gut NETs. Mid-gut NET is a rare disease and to perform randomised phase III trials necessitated a joint effort by many investigators. The positive outcome of this study will most likely influence future clinical practice."

More information: Abstract no: LBA 6. "177-Lu-Dotatate significantly improves progression-free survival in patients with mid-gut neuroendocrine tumours: Results of the phase III NETTER-1 trial". Presidential session II, 14.45-16.55 hrs (CEST), Sunday 27 September, Hall D1.

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